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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,904

01/16/2004

Eric J. Beckman

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1518

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,904	<b>Applicant(s)</b> BECKMAN ET AL.	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-69 and 104-112 is/are pending in the application.
- 4a) Of the above claim(s) 12-14,17 and 27-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,15,16,18-26,69 and 104-112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants amendments to the claims filed 12/21/2009 have been entered. Because applicants previously established that their polymer is a porous foam and defined the polymer as the product of the process defined in the claims the removal of the recitation of "polyurethane" is not considered new matter by the examiner since the polymer product was always defined by the reactants used to make the product itself.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1,3-11,15-16,18-20,22,25,69,104-11 and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by Beckman et al. (US 7,264,823 B2), for the reasons set forth in the office action filed 11/30/2007.**

**Claims 1,3-4,7-8,12,19,22,27-30,33,69,104-105,108 and 109 are rejected under 35 U.S.C. 102(e) as being anticipated by Woodhouse et al. (US 6,221,997 B1), for the reasons set forth in the office action filed 11/30/2007.**

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1,3-11,15-16,18-26,69 and 104-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (Biomaterials 21 (2000) 1247-1258) in view of Liptova et al. (Macromol. Symp. 152, 139-150 (2000)) or in view of**

**Woodhouse et al. (US 6,221,997 B1)**, for the reasons set forth in the office action filed 11/30/2007.

***Response to Arguments***

Applicant's arguments filed 12/21/2009 have been fully considered but they are not persuasive.

Applicants assert that none of the references above describe the reaction between a multifunctional isocyanate with a bioactive agent in water. Applicants assert that water exerts an effect on the reaction in that it acts as a chain extender; therefore the examiner cannot ignore the limitation as this leads to a patentable distinction in the chemical composition and physiochemical properties of the polymer.

The examiner respectfully disagrees. Applicant's arguments revolve around their belief that the chain extender water leads to a patentable difference over the prior art cited above in regards to the chemical composition and physiochemical properties of the polymer. However as currently amended there is no physical or chemical differences claimed to preclude the prior art cited above. The examiner notes that applicant's claims are drawn to a polymer composition formed from the reaction of an isocyanate, water as a chain extender and a bioactive agent. Whatever role water plays in the reaction sequence it does not change the chemical structure, the fundamental repeat unit  $(-RNHCOOR-)_n$  or  $(-RNHCONHR-)_n$  of the polymer formed by the reactants claimed. Applicants have not met their burden to explain how their claimed polymers structure would be different than that of the prior art. While the limitation detailing the use of aliphatic isocyanates and a bioactive agent containing at least one reactive group

Art Unit: 1618

must be considered by the examiner since their use changes the structure of the polymer, the chain extender, water does not change the chemical structure or physiochemical property of the polymer. Chain extenders are generally used in the art to functionalize the end groups of a macromolecule or prepolymer, allowing it to further react with another polymeric block, increasing the overall molecular weight of the polymer. Chain extenders are generally used to increase the molecular weight of a polymer; however applicants do not claim a molecular weight within their own claims that would preclude any of the references above. Thus the only physical characteristic of the polymer that would be affected by the chain extender water is not present within the claims. Furthermore applicants note at paragraph [0008] within their own specification that Zhang and coworkers used water as chain extenders for the prepolymers, Zhang also states that water is used as a chain extender within the abstract.

In regards to Beckman applicants assert that if Beckman used water in the reactions to form the adhesives it would not be capable of forming adhesive bonds since water would react with the isocyanate functionality, therefore there would be no diisocyanate end groups available for attachment.

Once again applicants are attempting to limit their composition by the process to make it not the product itself and not the product itself. If applicants believe there is a difference between their claimed polymer end group and Beckman then they should limit the end group of the polymer in the claims. As noted above the chain extender water does not change the fundamental polymeric formula of the polyurethane or

Art Unit: 1618

polyurea, water only serve to increase the molecular weight of the polymer itself, since applicants do not limit the molecular weight of their polymer the product by process limitation of using water as a chain extender bears no weight on the patentability of the product. As currently amended there is no limitation on the type of end group present on the polymer itself that would preclude Beckman.

Applicants assert that their claimed polymer composition is formed from the simultaneous reaction of the multi-functional isocyanate with bioactive agent and water.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., simultaneous reaction of multi-functional isocyanate with bioactive agent and water) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue in regards to Woodhouse that this reference does not teach reaction of an amine or an oligopeptide directly with a multi-functional isocyanate as presently claimed.

The relevance of this assertion is unclear; Woodhouse clearly teaches reacting a diisocyanate with a polyol (claimed as additional ingredient in claim 4) and a chain extender that includes an amino acid oligopeptides, meeting the claimed bioactive agent.

Applicants further assert there is no disclosure or suggestion within Zhang that details the reaction of a protein or any other bioactive agent with a multifunctional

Art Unit: 1618

isocyanate compound and Zhang does not even mention what is meant by incorporation of proteins and therefore is not enabled for attachment of proteins.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Clearly the examiner noted that Zhang while disclosing the peptide based urethane polymer may allow incorporation of proteins of interest such as cell attachment and/or growth factors but does not give any working examples, which is why the reference was combined with the other two other references in a 103(a) obviousness type of rejection. Clearly Zhang suggest incorporating proteins of interest in the peptide based urethane polymer but since the reference is silent on how to specifically attach such proteins one of ordinary skill in the art would seek such knowledge in the prior art. Such disclosure is provided by the secondary references Liptova and Woodhouse who both describe incorporation of bioactive agents into polyurethane polymers. Thus one of ordinary skill in the art would have a high expectation of success in conjugating bioactive substances such as peptides and heparin in the polyurethanes of Zhang since such knowledge was well known at the time of applicants claimed invention as taught in Liptova and Woodhouse and Zhang suggest incorporating proteins in the peptide based polyurethane.

### **Conclusion**

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you



Art Unit: 1618

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618